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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,548	12/12/2003	Shyam S. Mohapatra	USF-T187XC1	4609

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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
04/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/734,548	**Applicant(s)** MOHAPATRA ET AL.	
	Examiner DANA SHIN	**Art Unit** 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 March 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-3,7-11,13 and 21-27*.
   Claim(s) withdrawn from consideration: *4-6,12 and 28-30*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/J. E. Angell/
Primary Examiner, Art Unit 1635

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments are essentially the same as those filed on August 21, 2007, which were found to be unpersuasive. Similar to the arguments filed on August 21, 2007, applicant argues that the specification as well as a number of prior art references disclose many PKC inhibitors that are representative of the claimed genus. From this argument, applicant states that "An ordinarily skilled artisan, having the benefit of the teachings of the subject specification, would reasonably expect that any agent that inhibited PKC would also be effective in inhibiting RSV infection in an animal", without substatiating her argument. Again, as repeatedly stated in previous Office actions, it is true that many PKC inhibitors, both chemical and peptide, were known in the art at the time of the invention. However, the relationship between PKC inhibition and RSV treatment was not known in the art at the time of the invention. Again, the PKC inhibitors, which applicant alleges to be sufficient to represent the claimed genus, do not correspond in scope with the "claimed" invention, which is a method of inhibiting and treating RSV infection in a mammal. Furthermore, as expressly elected without traverse by applicant on February 27, 2007, the elected PKC inhibitor in the instant case is an interfering RNA. Applicant argues that siRNA structure targeted against PKC was known in the art, which was suggested to be used for the treatment of cancer and other diseases. It is true that the WO 03/070983 document disclosed PKC siRNA molecules;however, there is no teaching or suggestion that any of the disclsoed PKC siRNA molecules has the ability to inhibit RSV infection in a mammal. In fact, there is not even an animal in vivo example that shows that the administration of PKC siRNA into the mammal results in the inhibition of PKC activity said mammal. Applicant further aruges that since so many PKC inhibitors were known in the art including siRNA molecules, the instant specificaiton need not dislcose any of them. To reiterate, the specification does not even disclose the strucutre of the claimed siRNA that inhibits PKC activity in a mammal, which consequently inhibits and treats RSV infection and alleviates at least one RSV infection symptom in said mammal, as claimed in the instant case. Accordingly, the diclsoure of the chemical compound RO318220 tested in cells in vitro is not a representative number of species for the claimed PKC inhibitor (in particular, for the siRNA claimed in claims 21-27) that inhibits and treats RSV infection in a mammal, and nor does it show structure/function correlation for the claimed genus. Hence, claims 1-3, 7-11, 13, and 21-27 remain rejected as failing to comply with the written description requirement.

With regard to the enablement rejection, applicant argues that the state of the art was sufficiently developed to allow one of ordinary skill in the art to arrive at the claimed invention without undue experimentation. Applicant further asserts that RNAi technoloogy was not a nascent technology as of the earliest effective filing date of the instant application, which is granted only insofar as December 12, 2003, by providing a mere list of RNAi-related references that were published in 2002 and 2003. Again, none of the references are commensurate in scope with the claimed invention; that is, none of them teaches that inhibition of PKC in a living mammal results in treatment/inhibiton/allevation of RSV infection in said mammal. Moreover, the Milhavet et al. reference, which applicant heavily relies on, does not even mention the claimed disease "RSV infection". Again, the state of RNAi technology was nascent, contrary to applicant's allegation, as of the ealirest filing date sought in the instant application, because there was no teaching in the RNAi art as of December 12, 2003, that siRNA molecules can inhibit viral infection and alleviate symptoms in a mammal, let alone an siRNA targeted against PKC can inhibit RSV infection in a mammal. Applicant's arguments are all drawn to general teachings and concepts of RNAi technology, and none of the references provides a specific, useful teachings that corresponds in scope with the claimed invention. Also, it was noted in the previous Office action that consel's arguments and opinions without supporting factual evidence do not advance the issue of enablement. Applicant is again advised to refer to MPEP §2164. Applicant also asserts that no FDA approval is required to comply with the enablement requirement. This issue was never raised in any of the Office actions issued previously, therefore, applicant's such argument is irrelevant. In fact, it was clearly stated that "the invention must have been sufficiently tested to demonstrate that it will work for its intended purpose, but it need not be in a commercially satisfactory stage of development." See page 9 of the Office action mailed March 21, 2007. Hence, examiner does not understand the sources of applicant's allegation. Hence, claims 1-3, 7-11, 13, and 21-27 remain rejected as failing to comply with the enablement requirement. It is also noted that applicant's arguments for the pending rejections are essentially the same in content as those filed on August 21, 2007. Thus, applicant is also advised to refer to previous Office actions dated March 21, 207 and September 26, 2007.